Exhibit D

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April 11, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
Attn: Jenne Liu, RN, MSN
P.O. Box 3002
Rockville, Maryland 20847-3002

RE: Manufacturer Report Number: 2020394-2006-00018

Dear Ms Liu:

On March 23, 2006, Bard Peripheral Vascular, Inc. (BPV), a division of C.R. Bard, Inc. submitted a response to your request for additional information, dated February 7, 2006, concerning Manufacturer's MedWatch Report Number, 2020394-2006-00018. BPV subsequently identified that certain information was erroneously omitted from item 4 of the response. In an effort to provide clarification and ease of review, item 4 is underlined and is followed by BPV's original response. The additional information is noted in bold font.

<u>4. State the expected and observed frequency and severity of occurrence for the reported incident with this device.</u>

As defined in the Design Failure Modes and Effects Analysis (DFMEA) for this product, the original expected frequency of occurrence was less than or equal to 0.05% (1 in 2000). The observed frequency of occurrence for this severity level is 0.067% (6 in 8942), as of February 28th, 2006. As the actual rate of occurrence exceeds the expected rate, the level of risk for this specific failure mode was reassessed in the DFMEA. Upon secondary assessment, the overall risk level, which consists of occurrence, severity, and detection, remains below the risk threshold. The risk remains at an acceptable level ***per BPV's Risk Management System.***

BPV established a low internal threshold for migration in order to trigger formal monitoring of reported events that exceed the expected frequency and severity of occurrence. For the clinically relevant threshold (2%) for migration, one should consider the Society of Interventional Radiologists' (SIR) Quality Improvement Guidelines[1] (see Attachment A).

[1] Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

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Table 1: G2 Filter Migration Rate vs. SIR Guidelines Event/Threshold Rates

Potential Complications	*G2 Filter Rate Based on U.S. Sales*	*Complications/ Trackable Event Rates from SIR Guidelines[1] (all filters)**	*Threshold % from SIR Guidelines (all filters)***
Movement/Migration (2 cm+)	*0.067%*	*0-18%*	*2%*

** Suggested threshold for individual practices for purposes of case review*
*** Migration/Movement includes filter embolization as described in the SIR Guidelines*

Per Table 1 above, BPV's overall migration rate is within the range of reported (0-18%) and below the threshold (2%) rates, as described in the SIR Quality Improvement Guidelines. In conclusion, the G2 Filter migration rate is below the risk threshold per BPV's internal Risk Management System and is below the event rates and threshold reported in the SIR Quality Improvement Guidelines.

If you have any questions regarding this response, please do not hesitate to contact Cynthia Walcott by telephone at (480) 303-2747 or by fax at (480) 303-2774.

Kind Regards,

Cynthia Walcott

Cynthia Walcott, RN
Senior Manager, Clinical Assurance

ATTACHMENT A

Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

Clement J. Grassi, MD, Timothy L. Swan, MD, John F. Cardella, MD, Steven G. Meranze, MD, Steven B. Oglevie, MD, Reed A. Omary, MD, Anne C. Roberts, MD, David Sacks, MD, Mark I. Silverstein, MD, Richard B. Towbin, MD, and Curtis A. Lewis, MD, MBA, for the Society of Interventional Radiology Standards of Practice Committee

J Vasc Interv Radiol 2003; 14:S271–S275

Abbreviations: IVC = inferior vena cava, PE = pulmonary embolism

PULMONARY embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE (1–4). The current preferred treatment for deep venous thrombosis and PE is anticoagulation therapy. However, as many as 20% of these patients will have recurrent PE (1,5,6).

Interruption of the inferior vena cava (IVC) for the prevention of PE was first performed in 1893 with use of surgical ligation (7). Over the years, surgical interruption took many forms (ligation, plication, clipping, or stapling) but IVC thrombosis was a frequent complication after these procedures. Endovascular approaches to IVC interruption became a reality in 1967 after the introduction of the Mobin-Uddin filter (8).

Many devices have since been developed for endoluminal caval interruption but, currently, there are six devices commercially available in the United States. These devices are designed for permanent placement. For detailed information regarding each of these filters, the reader is referred to several published reviews (9–12). Selection of a device requires knowledge of the clinical settings in which filters are used, evaluation of the clot trapping efficiency of the device, occlusion rate of the IVC and access vein, risk of filter migration, filter embolization, structural integrity of the device, and ease of placement.

Percutaneous caval interruption can be performed as an outpatient or inpatient procedure. However, practically speaking, most filter placements will occur in the inpatient population because of ongoing medical therapy for acute thromboembolic disease or underlying illness.

The IVC should be assessed with imaging before placement of a filter, and the current preferred imaging method is vena cavography. Before filter selection and placement, the infrarenal IVC length and diameter should be measured, the location and number of renal veins determined, IVC anomalies (eg, duplication) defined, and intrinsic IVC disease such as preexisting thrombus or extrinsic compression excluded. The ideal placement for the prevention of lower extremity and pelvic venous thromboembolism is the infrarenal IVC. The apex or superior aspect of any filtration device should be at or immediately inferior to the level of the renal veins according to the manufacturers' recommendations. In specific clinical circumstances, other target locations may be appropriate.

Percutaneous caval interruption is commonly accomplished through right femoral and right internal jugular vein approaches; however, other peripheral and central venous access sites can be used. Filters can be placed in veins other than the vena cava to prevent thromboembolism. Implant sites have included iliac veins, subclavian veins, superior vena cava, and IVC (suprarenal and infrarenal). This document will provide quality improvement guidelines for filter placement within the inferior vena cava because of the limited data available for implantation sites other than the IVC. The patient's clinical condition, the type of filter available, the alternative access sites available, and the expertise of the treating physician should always be considered when the decision to place an IVC filter has been made.

These guidelines are written to be used in quality improvement programs to assess percutaneous interruption of the IVC to prevent pulmonary embolism. The most important processes of care are (*a*) patient selec-

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DOI: 10.1097/01.RVI.0000094597.83406.50

tion, (*b*) performing the procedure, and (*c*) patient monitoring. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Procedural Success: Deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural Failure: The procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death: Procedurally related death directly attributable to the filter itself documented by clinical findings, imaging, or autopsy.

Recurrent PE: Pulmonary embolism occurring after filter placement documented by pulmonary arteriography, cross sectional imaging, altered ventilation-perfusion lung scan to high probability of PE, or autopsy.

IVC Occlusion: Presence of an occluding thrombus in the IVC occurring after filter insertion and documented by US, CT, MR imaging, venography, or autopsy.

IVC Penetration: Penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC demonstrated by CT, US, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter Embolization: Post-deployment movement of the filter to a distant anatomic site completely out of the target zone.

Migration: Filter migration defined as a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter Fracture: Any loss of structural integrity (ie, breakage or separation) of the filter documented by imaging or autopsy.

Insertion Problems: Filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside of the infrarenal IVC when the operators' intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access Site Thrombus: Occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site (13–17).

Other access site complications with clinical sequelae: Arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in: admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1). The complication rates and thresholds listed herein refer to *major* complications.

INDICATIONS

Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal deep venous thrombosis and one or more of the following (13–16):
   a. Contraindication to anticoagulation
   b. Complication of anticoagulation
   c. Failure of anticoagulation
      i. Recurrent PE despite adequate therapy
      ii. Inability to achieve adequate anticoagulation
2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE
3. Free-floating iliofemoral or IVC thrombus
4. Severe cardiopulmonary disease and deep venous thrombosis (eg, cor pulmonale with pulmonary hypertension)
5. Poor compliance with anticoagulant medications

Additional Indications for Selected Patients

1. Severe trauma without documented PE or deep venous thrombosis
   a. Closed head injury
   b. Spinal cord injury
   c. Multiple long bone or pelvic fractures
2. High-risk patients (eg, immobilized, intensive care patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism)

Suprarenal Filter Placement

1. Renal vein thrombosis
2. IVC thrombosis extending above the renal veins
3. Filter placement during pregnancy; suprarenal placement is also appropriate in women of childbearing age
4. Thrombus extending above previously placed infrarenal filter

Table 1
Complications

Complications	Reported Rates (%)	Threshold (%)
Death (7)	0.12	<1
Recurrent PE (17–22)	0.5–6	5
IVC Occlusion (11,17,19,20,23–27)	2–30	10
Filter Embolization (17,24,28–37)	2–5	2
Access Site Thrombosis—Major (see Appendix 1) (38,39)	0–6*	1

* Includes reported rates of both major and minor complications.

Table 2
Other Trackable Events

Other Trackable Events	Reported Rates (%)
IVC Penetration (7,17,19,23,27,40,52)*	0–41
Migration (7,9,10,17,19–21,26,41,42)*	0–18
Filter Fracture (17,24)	2–10
Access Site Thrombus	
All types (7,38,43,44)	0–25
Occlusive (38,45)	3–10
Insertion Problems (7,17,19–22,24,26,41,43,46,47)	5–50
Other complications (48,49)	1–15

Note.—The rate of clinically significant penetration is undefined in the literature (39,50,52).
* Clinically significant penetration and migration are believed to be rare.

5. Pulmonary embolism after gonadal vein thrombosis
6. Anatomic variants: duplicated IVC, low insertion of renal veins

RELATIVE CONTRAINDICATIONS (TO PERCUTANEOUS PLACEMENT)

1. Uncorrectable severe coagulopathy (eg, patients with liver or multisystem failure).
2. Caution should be exercised when placing a filter in patients with bacteremia or untreated infection; clinical judgement should be applied in these situations weighing the theoretical risk of implant infection versus the risk of PE.

For pediatric and young adult patients, filter placement indications should be strict because the long-term effects and durability of the devices are not precisely known.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

SUCCESS

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

COMPLICATIONS

Each currently available filter has been studied extensively as part of the Food and Drug Administration approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines will not suggest threshold rates for each individual filter; rather, filtration devices will be considered as a group (**Table 1**).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to exceed a complication-specific threshold when the complication occurs in a small volume of patients, for example, early in a quality improvement program (18–52).

OTHER TRACKABLE EVENTS

Because an IVC filter is a permanent implantable device and because this device is sometimes placed in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

Acknowledgments: Clement Grassi, MD, and Timothy Swan, MD, authored the first draft of this document and served as topic leaders during the subsequent revisions of the draft. Dr. John Cardella is chair of the SIR Standards of Practice Committee. Curtis Lewis, MD, MBA, is Councilor of the SIR Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are John E. Aruny, MD, Curtis Bakal, MD, MPH, Dana Burke, MD, Paramjit Chopra, MD, Steven J. Citron, MD, Patricia E. Cole, PhD, MD, Martin Crain, MD, Andrew Davis, MD, Alain Drooz, MD, Elizabeth Drucker, MD, JD, Neil Freeman, MD, Jeff Georgia, MD, Richard Shlansky-Goldberg, MD, Richard Gray, MD, Sue Hanks, MD, Ziv Haskal, MD, James Husted, MD, Michael Todd Jones, MD, Patrick C. Malloy, MD, Louis Martin, MD, Timothy C. McCowan, MD, Theodore Mirra, MD, Sally Mitchell, A. Van Moore, MD, Calvin D. Neithamer, MD, Nilesh Patel, MD, Paravati Ramchandani, MD, Kenneth S. Rholl, MD, Orestes

Sanchez, MD, Harjit Singh, MD, Bob Smouse, MD, Patricia Thorpe, MD, Scott Trerotola, MD, Anthony Venbrux, MD, and Daniel Wunder, MD.

APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Result in no therapy, no consequence, or

B. Result in nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours),

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours),

E. Cause permanent adverse sequelae, or

F. Cause death

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from standards of practice committee member practices and, when available, the SIR HI-IQ® system National Database. Consensus on statements in this document was obtained with use of a modified Delphi technique (53,54).

Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism

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A complete list of the members of the SIR Standards of Practice Committee is given at the end of this article. **Address correspondence to** SIR, 10201 Lee Hwy, Suite 500, Fairfax, VA 22030.

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DEFINITIONS

Procedural Success: Deployment of a filter such that the filter is judged suitable for mechanical protection against PE.

Procedural Failure: The procedure concludes with unsatisfactory filter deployment such that the patient has inadequate mechanical protection against PE.

Death: Procedurally related death directly attributable to the filter itself documented by clinical findings, imaging, or autopsy.

Recurrent PE: Pulmonary embolism occurring after filter placement documented by pulmonary arteriography, cross sectional imaging, altered ventilation-perfusion lung scan to high probability of PE, or autopsy.

IVC Occlusion: Presence of an occluding thrombus in the IVC occurring after filter insertion and documented by US, CT, MR imaging, venography, or autopsy.

IVC Penetration: Penetration of the vein wall by filter hooks with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration is filter strut or anchor devices extending more than 3 mm outside the wall of the IVC demonstrated by CT, US, venography, or autopsy. Acute penetration occurring during placement of the filter is considered an insertion problem (see below).

Filter Embolization: Post-deployment movement of the filter to a distant anatomic site completely out of the target zone.

Migration: Filter migration defined as a change in filter position compared to its deployed position (either cranial or caudal) more than 2 cm as documented by plain film imaging, CT, or venography.

Filter Fracture: Any loss of structural integrity (ie, breakage or separation) of the filter documented by imaging or autopsy.

Insertion Problems: Filter or deployment system related malfunctions such as incomplete filter opening, filter tilt more than 15° from the IVC axis (eg, non–self-centering filters), misplacement of filter outside of the infrarenal IVC when the operators' intent is to place the filter in the infrarenal IVC (eg, when a portion of the filter is within one iliac vein), or prolapse of filter components. Filter malposition requiring surgical removal is considered an insertion problem complication.

Access Site Thrombus: Occlusive or nonocclusive thrombus developing after filter insertion at the venotomy site (13–17).

Other access site complications with clinical sequelae: Arteriovenous fistula, hematoma, or bleeding requiring a transfusion, hospitalization (either admission or extended stay), or further treatment for management.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications); in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold a review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in: admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 1). The complication rates and thresholds listed herein refer to *major* complications.

INDICATIONS

Accepted

1. Patients with evidence of pulmonary embolus or IVC, iliac, or femoral-popliteal deep venous thrombosis and one or more of the following (13–16):
   a. Contraindication to anticoagulation
   b. Complication of anticoagulation
   c. Failure of anticoagulation
      i. Recurrent PE despite adequate therapy
      ii. Inability to achieve adequate anticoagulation
2. Massive pulmonary embolism with residual deep venous thrombus in a patient at risk for further PE
3. Free-floating iliofemoral or IVC thrombus
4. Severe cardiopulmonary disease and deep venous thrombosis (eg, cor pulmonale with pulmonary hypertension)
5. Poor compliance with anticoagulant medications

Additional Indications for Selected Patients

1. Severe trauma without documented PE or deep venous thrombosis
   a. Closed head injury
   b. Spinal cord injury
   c. Multiple long bone or pelvic fractures
2. High-risk patients (eg, immobilized, intensive care patients, prophylactic preoperative placement in patients with multiple risk factors for venous thromboembolism)

Suprarenal Filter Placement

1. Renal vein thrombosis
2. IVC thrombosis extending above the renal veins
3. Filter placement during pregnancy; suprarenal placement is also appropriate in women of childbearing age
4. Thrombus extending above previously placed infrarenal filter

Table 1
Complications

Complications	Reported Rates (%)	Threshold (%)
Death (7)	0.12	<1
Recurrent PE (17–22)	0.5–6	5
IVC Occlusion (11,17,19,20,23–27)	2–30	10
Filter Embolization (17,24,28–37)	2–5	2
Access Site Thrombosis—Major (see Appendix 1) (38,39)	0–6*	1

* Includes reported rates of both major and minor complications.

Table 2
Other Trackable Events

Other Trackable Events	Reported Rates (%)
IVC Penetration (7,17,19,23,27,40,52)*	0–41
Migration (7,9,10,17,19–21,26,41,42)*	0–18
Filter Fracture (17,24)	2–10
Access Site Thrombus	
All types (7,38,43,44)	0–25
Occlusive (38,45)	3–10
Insertion Problems (7,17,19–22,24,26,41,43,46,47)	5–50
Other complications (48,49)	1–15

Note.—The rate of clinically significant penetration is undefined in the literature (39,50,52).
* Clinically significant penetration and migration are believed to be rare.

5. Pulmonary embolism after gonadal vein thrombosis
6. Anatomic variants: duplicated IVC, low insertion of renal veins

RELATIVE CONTRAINDICATIONS (TO PERCUTANEOUS PLACEMENT)

1. Uncorrectable severe coagulopathy (eg, patients with liver or multisystem failure).
2. Caution should be exercised when placing a filter in patients with bacteremia or untreated infection; clinical judgement should be applied in these situations weighing the theoretical risk of implant infection versus the risk of PE.

For pediatric and young adult patients, filter placement indications should be strict because the long-term effects and durability of the devices are not precisely known.

The threshold for these indications is 95%. When fewer than 95% of procedures are performed for these indications, the department will review the process of patient selection.

SUCCESS

It is expected that the technical success for percutaneously placed IVC filters will be 97% or better in experienced hands. Therefore, the proposed threshold for review of technical failures should be 3%.

COMPLICATIONS

Each currently available filter has been studied extensively as part of the Food and Drug Administration approval process. Few comparative studies have been completed evaluating all filters in one project, and those that have done so have been retrospective analyses. Complication rates are highly variable depending on the filter being studied. For simplicity, these guidelines will not suggest threshold rates for each individual filter; rather, filtration devices will be considered as a group (**Table 1**).

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. It is also recognized that a single complication can cause a rate to exceed a complication-specific threshold when the complication occurs in a small volume of patients, for example, early in a quality improvement program (18–52).

OTHER TRACKABLE EVENTS

Because an IVC filter is a permanent implantable device and because this device is sometimes placed in relatively young patients, several other trackable parameters when observed are appropriate to record in a quality improvement program. The events listed in **Table 2** may or may not be clinically significant in a particular patient. For this reason, thresholds for these events are not included in this document.

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APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

A. Result in no therapy, no consequence, or

B. Result in nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours),

D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours),

E. Cause permanent adverse sequelae, or

F. Cause death

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from standards of practice committee member practices and, when available, the SIR HI-IQ® system National Database. Consensus on statements in this document was obtained with use of a modified Delphi technique (53,54).

Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.